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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/848,811	05/04/2001	Todd H. Rider	01997-227003	8505

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EXAMINER
CHIN, CHRISTOPHER L

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 08/26/2003

4

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/848,811	Rider et al
Examiner	**Art Unit**
Chris Chin	1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *May 4, 2001*

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-3, 6-11, and 14-17* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideratio

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-3, 6-11, and 14-17* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examine

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Specification

1. The disclosure is objected to because of the following informalities:

a.) The status of the parent application needs to be updated on page 1 of the specification.

Appropriate correction is required.

Claim Rejections - 35 U.S.C. § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-3, 6-11, and 14-17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for B-cells and fibroblasts, does not reasonably provide enablement for the use of any other types of cells in the claimed device. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. Factors to be considered in determining whether a disclosure would require undue experimentation include (1) the nature of the invention, (2) the

state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

The nature of the invention - the claimed invention is a device for detecting the presence of one or more antigens comprising (1) a cell having antibodies which are expressed on the surface of the cell and are specific for the antigen to be detected, wherein binding of the antigen to the antibodies results in an increase in calcium concentration in the cytosol of the cell, the cell further having an emitter molecule which, in response to the increased calcium concentration, emits a photon; (2) a liquid medium in which the cell is immersed and receives the antigen to be detected; and (3) an optical detector arranged for receiving the photon emitted from the cell. For the detection of more than one antigen, the device comprises an array of sectors wherein each sector contains a cell expressing antibodies on its surface for one of the antigens.

The state of the prior art - the prior art does not disclose a device with the specific limitations of the claimed invention.

The predictability or lack thereof in the art - there is low predictability in the art because the specification only discloses B-cells and fibroblasts as the cells with the required ability to express antibodies on their surface that are specific for an antigen and contain an emitter molecule that emits a photon in response to an increase in calcium levels in the cell when antigen binds to the antibodies on the cell surface.

The amount of direction or guidance present - the specification (first paragraph on page 2) teaches the use of B-cells and fibroblasts as the only specific cells that are capable of expressing antibodies on their surface that are specific for the antigen(s) that are to be detected in the claimed device and can emit a photon to provide an indication that antigen have bound to the antibodies. Page 3 of the specification teaches that the cells can be prokaryotic or eukaryotic but only teaches B-cells and fibroblasts as examples of the cells that can be used in the claimed device. The specification fails to teach any other cells that can be used in the claimed device with the required abilities of expressing antibodies on their surfaces that can specifically bind to a desired antigen and emit a photon in response to antigen binding to the antibodies.

The presence or absence of working examples - Example 2 on page 9 of the specification exemplifies the use of B-cells in the claimed device and Example 3 on page 11 of the specification exemplifies the use of fibroblasts in the claimed device. The specification lacks any other working examples of the claimed device using cells other than B-cells or fibroblasts.

The quantity of experimentation necessary - since the specification lacks any teachings or suggestions as to other viable cells, aside from B-cells and fibroblasts, that can be used in the claimed device having the required ability of expressing antibodies on their surface that are specific for a desired antigen and can emit a photon in response to antigen binding to the antibodies, an undue amount of experimentation would be required.

The relative skill of those in the art - the level of skill in the art is high.

The breadth of the claims - the instant claims are directed to a device that utilizes any cell that can express antibodies on their surface that specific for the antigen that is to be detected and emits a photon in response to antigen binding to the antibodies.

The instant specification is not broadly enabled for the use of any cell in the device as recited in the instant claims. The specification only teaches B-cells and fibroblasts as the cells with the required ability to express antibodies on their surfaces that can specifically bind to the antigen that is to be detected and emit a photon in response to antigen binding to the antibodies. The specification fails to teach or suggest other cells with the abilities recited in the instant claims.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground

provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1-3 and 6-8 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 6,087,114. Although the conflicting claims are not identical, they are not patentably distinct from each other because patent '114 claims a device with essentially the same limitations as the instantly claimed device.

Patent '114 claims a device for detecting the presence of an antigen comprising a B-cell having antibodies expressed on its surface that can specifically bind to the antigen that is to be detected, a liquid medium in which the B-cell is immersed, and an optical detector. Binding of antigen to the antibodies results in an increase in calcium concentration in the cytosol of the B-cells. The B-cell contains an emitter molecule that emits a photon in response to the increase in calcium concentrations.

The device in patent '114 differs from the instant invention in reciting the use of B-cells in the device instead of generically reciting the use of any cell.

However, it would have been obvious to one of ordinary skill in the art that the use of B-cells in the '114 patent is encompassed by the broad recitation of any cell in the instant claims.

6. Claims 1-3, 6-11, and 14-17 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 6,248,542. Although the conflicting claims are not identical, they are not patentably distinct from each other because patent '542 claims a device with essentially the same limitations as the instantly claimed device.

Patent '542 claims a device for detecting the presence of an antigen comprising a fibroblast having antibodies expressed on its surface that can specifically bind to the antigen that is to be detected, a liquid medium in which the fibroblast is immersed, and an optical detector. Binding of antigen to the antibodies results in an increase in calcium concentration in the cytosol of the fibroblasts. The fibroblast contains an emitter molecule that emits a photon in response to the increase in calcium concentrations. Patent '542 also claims a device for detecting two or more antigens wherein an array of fibroblasts is used. Each fibroblast is specific for a different antigen.

The devices in patent '542 differ from the instant invention in reciting the use of fibroblasts in the device instead of generically reciting the use of any cell.

However, it would have been obvious to one of ordinary skill in the art that the use of fibroblasts in the '542 patent is encompassed by the broad recitation of any cell in the instant claims.

Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chris Chin whose telephone number is (703) 308-3991. The examiner can normally be reached on Monday-Thursday from 10:00 am to 7:30 pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (703) 305-3399.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Christopher L. Chin

cchin/cc
August 23, 2003

CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP ~~1800~~ 1641